Section 8 – Special 510(k) Summary

JUL 1 8 2013

I. General Information

Submitter:

Incisive Inc.

Contact Person:

Michael Yessik

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510-669-9401

Summary Preparation Date: June 11, 2013

II. Names

Device Name(s): InPulse Laser

Primary Classification Name(s): Electrosurgical cutting and coagulation device and accessories

III. Predicate Devices

- K093547 – PinPointe FootLaser and Accessories

IV. Product Description

The InPulse Laser is comprised of the following main components:

- **Main console** containing the major electrical components, including:
  - Control/ Display Panel with the:
  - Keyswitch (that controls authorized access to the laser system);
  - emergency Laser Stop button;
  - Displays (laser emission indicator, average power, pulse energy,
  - repetition rate)
  - LCD screen user interface permitting selection of treatment
  - emission when the footswitch is depressed and a fiber optic is properly
  - attached);
- 1064 nm treatment laser (solid state Nd:YAG laser rod) with flashlamp and associated light regulation components and electronics;
- 630 -680 nm (red) aiming beam diode laser;
- Delivery device fiber-optic connector port;
- Remote interlock connector (External door interlock connector);
- Connector ports for the footswitch and power cord;
- Accessory holder (attached to the rear of the main console);
- Footswitch;
- Medical grade power cord;
- Delivery Devices for Non-Contact and Contact with Intact Skin/Tissue:
  - Guide Tip - No Standoff: Reusable, cleanable, tip is provided for noncontactuse to direct and control the placement of the laser beam (free beam) at the treatment location. The Guide tipattaches to the end of the handpiece. The optical fiber is threaded through the handpiece and fits securely into the bore of the Guide tip;
  - Guide Tip - With Standoff: Reusable, cleanable, tip is provided for minimal-contact with intact skin/ tissue to direct and control the placement of the laser beam at the treatment location. The Guide tip attaches to the end of the handpiece. The optical fiber is threaded through the handpiece and fits securely into the bore of the Guide tip;
- Delivery Devices for Contact with Breached Surfaces:
  - Optical Fibers - Reusable, cleanable, sterilizable optical fibers (range of 200 – 1000 um diameter) provided non-sterile, clean and ready for sterilization (steam autoclave).
  - Handpieces - Reusable, cleanable, sterilizable handpieces (large and small diameter shafts) provided non-sterile, clean and ready for sterilization (steam autoclave). The optical fiber is threaded through the handpiece and secured and held in place with the handpiece locking cap;
  - Handpiece Tips - Disposable single-use tips are provided in straight and curved configurations and are used to direct and control the placement of the optical fiber tip at the treatment location. The handpiece tips attach to the end of the handpiece. The optical fiber is threaded through both the handpiece and the handpiece tip;
- Accessories:
- Safety Glasses
- Tools:
  - Optical Fiber Striper;

- Optical Fiber Cleaver (carbide wedge, ceramic, or equivalent scribe for cleaving the optical fibers).

V. Indications for Use

Indications for Use (same as K093547):

The InPulse Laser and the delivery accessories that are used with them are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in the medical specialties of general and cosmetic dentistry, otolaryngology, ENT surgery, and dermatology & plastic surgery including intraoral soft tissue dental surgery, oral maxillo-facial and cosmetic surgery, general surgery, E.N.T. surgery, podiatry, and dermatology and plastic surgery.

Podiatry

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
- Periungual and subungual warts
- Plantar warts
- Radical nail excision
- **Neuromas**

The InPulse Laser is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans,* etc.).

Dermatology and Plastic Surgery

Dermatology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Lesions of skin and subcutaneous tissue
- Telangiectasia
- Port wine lesions
- Spider veins
- Hemangiomas
- Plantar warts
- Periungual and subungual warts
- Removal of tattoos
- Debridement of decubitus ulcer
- Treatment of keloids

Oropharangeal/ Dental Surgery Indicated for:

- Abscess incision and drainage
- Aphthous ulcers treatment
- Biopsies, excisional and incisional
- Crown lengthening
- Exposure of unerupted *I* partially erupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty
- Hemostasis
- Implant removal
- Lesion (tumor) removal
- Leukoplakia
- Operculectomy
- Oral papillectomy
- Pulpotomy
- Pulpotomy as adjunct to root canal therapy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal re-treatment
- Selective ablation of enamel (first degree) caries removal
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility
- Tissue retraction for impressions
- Vestibuloplasty

General Surgery Indicated for:

Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Cholecystectomy
- Lymphadenectomy
- Mastectomy
- Partial nephrectomy
- Hepatectomy
- Pilonidal cystectomy
- Pancreatectomy
- Resection of lipoma
  Splenectomy
- Pelvic adhesiolysis
- Hemorrhoidectomy
- Removal of lesions
- Thyroidectomy
- Removal of polyps
- Parathyroidectomy

- Removal of tumors
- Herniorrhaphy
- Tumor biopsy
- Tonsillectomy
- Debridement of decubitus ulcers
- Appendectomy

Endonasal Surgery
Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
- Lesions or tumors of the oral, nasal, glossal, pharyngeal & laryngeal tissues
- Tonsillectomy
- Adenoidectomy

No clinical data was needed for these indications. They are identical to those on K093547.

VI. Summary of Technological Characteristics

The technological characteristics of the InPulse Laser are substantially equivalent to those of the predicate device.

Characteristic	InPulse Laser	K093547 PinPointe FootLaser
Product Code Regulation	General & Plastic Surgery • GEX, 21 CFR 878.4810	General & Plastic Surgery • GEX, 21 CFR 878.4810
Intended Use	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures
Indications for Use	Exactly the same as K093547	See K093547
Wavelength	1064nm	1064nm
Aiming beam	630-680 nm (< 2.5 mW)	630-680 nm (< 2.5 mW)
Power Watts	6W, 30W, 100W	6W, 30W, 100W
Pulse Duration (usec)	100-700 (6W), 350-3000(30W), 350-3000 (100W)	100-700 (6W), 350-3000(30W), 350-3000 (100W)

Characteristic	InPulse Laser	K093547 PinPointe FootLaser
Energy per pulse (mJ)	20-200 (6W), 20-1000 (6W), 20-3500 (1ooW)	20-200 (6W), 20-1000 (6W), 20-3500 (1ooW)
Output Mode	Pulsed, multi mode	Pulsed, multi mode
Repetition rate	5-100Hz	5-100Hz
Laser media	Flashlamp pumped, solid state laser rod	Flashlamp pumped, solid state laser rod
User interface	LCD screen	Push button panel
Laser activation	footswitch	footswitch
Delivery devices, how supplied	Non-sterile, reusable, cleanable, sterilizable	Non-sterile, reusable, cleanable, sterilizable
Electrical requirements	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the InPulse Laser is substantially equivalent to the predicate device and is safe and effective for use for the various indications for use stated.

VIII. Conclusion

The InPulse Laser was found to be substantially equivalent to the predicate device.

The InPulse Laser shares identical indications for use, similar design features, and functional features with, and thus are substantially equivalent to, the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Incisive, Inc.
% Ms. Kathy Maynor
Regulatory Consultant
26 Rebecca Court
Homosassa, Florida 34446

July 18, 2013

Re: K131805
Trade/Device Name: InPulse Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 11, 2013
Received: June 19, 2013

Dear Ms. Maynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: InPulse Laser

Indications for Use **(same as K093547):**

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The InPulse FootLaser is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes,* and/or yeasts *Candida albicans,* etc.).

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

_____

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K131805

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Indications for Use Statement (continued)

510(k) Number (if known): _____

Device Name: InPulse Laser

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- Telangiectasia
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- Spider veins
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- Removal of tattoos
- Debridement of decubitus ulcer
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- Fibromfl removal
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- Frenotomy
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty

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Division of Surgical Devices

510(k) Number K131805

K131805

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Indications for Use Statement (continued)

510(k) Number (if known): _____

Device Name: InPulse Laser

Oropharangeal/ Dental Surgery- Continued
Indicated for:

- Hemostasis
- Implant removal
- Lesion (tumor) removal
- Leukoplakia
- Operculectomy
- Oral papillectomy
- Pulpotomy
- Pulpotomy as adjunct to root canal therapy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal re-treatment
- Selective ablation of enamel (first degree) caries removal
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- Hepatectomy

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510(k) Number K131805

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510(k) Number (if known): _____

Device Name: InPulse Laser

Indications for Use- Continued:

General Surgery- Continued Indicated for:

- Pilonidal cystectomy
  Pancreatectomy Resection
  oflipoma Splenectomy
- Pelvic adhesiolysis
  Hemorrhoidectomy
  Removal of lesions
  Thyroidectomy
  Removal of polyps
  Parathyroidectomy
  Removal of tumors
  Herniorrhaphy Tumor
  biopsy Tonsillectomy
- Debridement of decubitus ulcers
- Appendectomy

Endonasal Surgery

Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Lesions or tumors of the oral, nasal, glossal, pharyngeal & laryngeal tissues
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